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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,922	09/05/2003	Jose Luis Moctezuma de la Barrera	29997/062	8618

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MCCRACKEN & FRANK LLP
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EXAMINER

SHAY, DAVID M

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/655,922

Applicant(s)

MOCTEZUMA DE LA BARRERA ET AL.

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 12, 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-122 is/are pending in the application.
- 4a) Of the above claim(s) 54-88 and 107-122 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-53 and 89-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 12, 2006 has been entered.

Applicant traverses the examiner's objection to the drawings, asserting that the legend "Virtual Trial" satisfies the examiner's requirement because determining the range of motion is mentioned in the specification as part of the virtual trial. The examiner cannot agree. If the details of a procedure or device are claimed, they must be illustrated. A claim to an automobile including rods, pistons, water jackets and intake manifold would not be properly illustrated by a figure with an automobile having a block labeled only "Engine" – the claimed elements must be shown, this is not satisfied by the mere illustration of a block with a label of an entire system or procedure when components thereof are claimed.

Applicant argues that Carson et al is not applicable to the claims because of the do not disclose the construction of a model intraoperatively. The examiner must respectfully disagree. Applicant is respectfully reminded that the disclosures of the prior art are evaluated for what it would teach person having ordinary skill in the art and as such, the disclosure regarding imageless systems which is discussed as "resulting in longer operating room time" is clearly done intraoperatively. As to applicant's assertions regarding the prior art systems, the examiner notes that Carson et al also teach the use of such systems in column 12, lines 19-49 thereof. It is further noted that the model of Carson is constructed without the use of the three dimensional image, although it is used therewith subsequently. Further it appears that the claimed method is

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essentially the Carson et al method without the use of images, and as such it would have been obvious to omit that element along with its function in the method of Carson et al. With regard to the term “modeling” the examiner notes that no affidavit is necessary. The claims are to be read with the terms being given their broadest reasonable interpretation. As applicant has provided no specific definition to be assigned to the term “modeling” the interpretation of this term in the claims falls under the aforementioned doctrine. Webster’s Dictionary defines “model” as “to represent as a model; to describe in detail.” It is clear not only from the disclosure to “define the complex anatomical geometries of the knee” but also from the Carson et al disclosure at column 12, lines 35–39 “the center of rotation can be established by using the probe and designation a number of points on the femoral head and thus allowing the computer to calculate the geometrical center...” that “modeling” within the broadest reasonable interpretation of the term, is being performed by Carson et al. Since Carson et al also state that the center of rotation is determined for the purposes of establishing the mechanical axes and other relevant constructs relating to the femur, it is also clear that the claimed axes are also determined thereby.

Lastly, with regard to applicant’s comments directed towards DiGioia et al (NPL), the examiner stated the DiGioia et al (NPL) did not teach producing a three dimensional model, *per se*. That is DiGioia et al (NPL) does not state *ipsis verbis* that this is done. It is the examiner’s view that the production of the cloud of points, which is then matched to the “geometric description of the bony surface” falls within the broadest reasonable interpretation of the term “modeling”, even though DiGioia et al (NPL) does not use that term.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “determining joint range of

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motion of the joint” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The amendment filed December 12, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: “constructing a three dimensional model of the joint intraoperatively ...without using a scan...”

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-53 and 89-106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure and the disclosure as amended is silent on "constructing a three dimensional model of the joint intraoperatively ...without using a scan..." and is further silent on the manner in which this is done to overcome the deficiencies of the prior art which employs this technique.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-53 and 89-106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the claims, the exact meaning of the term "scan" is unclear, given that the surgical navigation system employed (see the originally filed disclosure, page 7, lines 24-25) uses scanning (see paragraphs [102] and [106] to [108] thereof).

Claims 1-5, 7, 8, 14, 15, 21-26, 28-32, 35, 41, 42, and 89-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al in combination with Salehi et al. Carson et al teach a method as claimed except for any discussion of the placement of the stem and use of the sagittal and coronal planes. Salehi et al teach the equivalence of stems and other means for

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attaching implants to the bones they are to be mounted on. It would have been obvious to the artisan or ordinary skill to employ an implant with a stem in the method of Carson et al since these are equivalent to other attachment means, as taught by Salehi et al, thus producing a method and method such as claimed.

Claims 1-12, 14-39, 41-53, and 89-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al as applied to claims 1-5, 7, 8, 14, 15, 21-26, 28-32, 35, 41, 42, and 89-93 above, and further in combination with DiGioia et al (NPL). DiGioia et al (NPL) teach a method as claimed except for the specific recitation of producing a three-dimensional model of the joint per se. It would have been obvious to the artisan of ordinary skill to provide the method of DiGioia et al (NPL) in the method of Carson et al, since this will provide a better fit and reduce the incidences of dislocations, as taught by DiGioia et al (NPL) or alternatively to include the three-dimensional rendering of the joint in of Carson et al in the method of DiGioia et al (NPL), since this would enable the more efficient and realistic determination of and visualization of the appropriate placement of the portions of the implant, thus producing a method such as claimed.

Claims 13 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al in combination with Salehi et al as applied to claims 1-5, 7, 8, 14, 15, 21-26, 28-32, 35, 41, 42, and 89-93 above or Carson et al in combination with DiGioia et al (NPL) as applied to claims 1-12, 14-39, 41-53, and 89-106 above, and further in view of Gustilo et al. Gustilo et al teach that relating the depth of the reaming to the depth of the medial wall maximizes the stability of the prosthesis. It would have been obvious to the artisan of ordinary skill to relate the depth of the reaming to the depth of the medial wall in the combined methods of Carson et al and Salehi

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et al and Carson et al and DiGioia et al (NPL) maximizes the stability of the prosthesis, as taught by Gustilo et al, thus producing a method such as claimed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-53 and 89-106 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-46 of copending Application No. 10/732,553. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific patent application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower

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invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1-53 and 89-106 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-35 of copending Application No. 11/148,520. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific patent application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection.

Applicant's arguments filed December 12, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

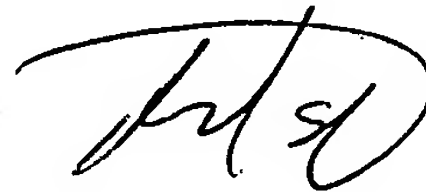
Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and

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Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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